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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,970	12/05/2001	Beom Kyu Kim	P21770	1401

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EXAMINER

HENDRICKS, KEITH D

ART UNIT	PAPER NUMBER
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1761

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/001,970

Applicant(s)

KIM ET AL.

Examiner

Keith Hendricks

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "mushroom ingredients-containing medium" is indefinite, due to the phrase "mushroom ingredients", as found in claims 1, 2, 5, 6, etc. As mushrooms are a product of nature, they are not composed of "ingredients", and thus it is unclear as to what is encompassed by the claim language. Reference to claim 2 states that the composition utilized in the invention is formed from either ground mushrooms or mushroom extract.

The phrase "mushroom extract", and the step of "extracting", for example as found in claims 2, 4, etc., are indefinite. It is unclear as to what, exactly, is "extracted" from the mushroom. There are no procedural steps indicated in the claims or the specification such that one skilled in the art would be apprised of what constituted a "mushroom extract". Furthermore, as extraction protocols are specifically tailored depending upon the targeted compound(s) to be extracted, this step and the resultant extract product are indefinite as claimed. For example, a single compound extracted from a mushroom may also be extracted as it exists in other organisms, as found in nature, and thus it would be the same compound, regardless of source. Note that this affects the metes and bounds of the claimed invention with respect to a comprehensive search of the prior art, as well.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are those involved in the production of the "mushroom ingredients-containing medium." The specification does not support the simple use of intact mushrooms, and thus they must be processed by some protocol prior to use within the claimed invention. In claim 1, for example, the step of preparing the medium requires the use of "mushroom ingredients"; however, the mode of obtaining this composition is not set forth. Dependent claim 2 does not necessarily resolve this issue. While the step of grinding is known and straightforward, the other option of "extracting" some unspecified composition ("mushroom ingredients") is not.

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Furthermore, step (ii) of claim 2 does not set forth the necessary process of adding or combining the obtained "mushroom ingredients" to the culture medium. Step (ii) of claim 2 simply recites "preparing a lactic acid bacteria medium", but does not set forth what is involved, while step (iii) presumes the formation of "the ingredients-containing medium of mushroom". See also page 9 of the specification.

In claim 1, part (b), the phrase "lactic acid strain" does not clearly set forth that this is a bacteria, which is necessary to carry out the invention.

In claim 1, parts (c) and (d) are unclear as to the actual protocol involved and necessary, as well as the practical difference between the two steps. Culturing an organism upon a medium generally involves conditions for promoting growth and/or maintenance of the culture, and yet would appear to also necessarily involve "aging", absent some additional distinguishing method steps not currently found within the claim. See instant claims 11-13.

In claims 7 and 9-10, the phrase "bacteria in cold storage or heat-treated lactic acid bacteria" is indefinite. Initially, it is unclear as to how a "bacteria in cold storage" may be used to inoculate the culture medium, as it would no longer be "in cold storage." Furthermore, it is unclear as to how this would correspond to the typical art-accepted terminology, such as "freeze-dried" or some other phrase common in the art. Similarly, it is unclear as to how a "heat-treated" bacteria would be expected to survive for culturing. These issues may be due, at least in part, to a translation from a foreign document. See claim 10, which utilizes the more accepted protocol step of incubating. However, claim 10 ultimately depends from claim 7, which recites either "cold storage" or "heat-treated" bacteria, but not the combination of both found in claim 10. Thus claim 10 also lacks support from the claim(s) from which it depends.

The recitation of the temperature ranges in claims 10 and 13 are indefinite. For example, the phrase "incubating the strain till a temperature ranging 25-40°C" is grammatically incorrect, and does not set forth if this is a targeted range of temperature, or if this is a range of difference of temperatures, with respect to some unspecified temperature point. Similarly, "at a temperature ranging 3-5°C" does not actually set forth at what temperature (or range) the step is carried out. Contrast this, for example, with the suggested phrase "at a temperature of from 3-5°C".

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Claims 15 and 17 are indefinite for the recitation of "effective ingredients", and the indicated resultant effects therein. Initially, it is unclear as to what these ingredients might be, and from where they are derived. Secondly, it is unclear for what purpose they are to be "effective". Further, it is unclear in what system (animal type) the resultant property is effected. Finally, claims 16 and 18 appear to indicate that the "effective ingredients" are found within the mushrooms themselves, yet this is not clear from claims 15 and 17, as these claims allow for any unspecified "effective ingredients" from any source.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 11, 14-15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakada (JP 11046684; computer translation provided).

Nakada discloses the production of a fermented liquid mixture of Enoki mushroom (*Flammulina velutipes*) extract, with milk, water and sugar. A mushroom extract is produced by grinding in water, and is added to milk, or skim milk powder, and a sugar (par. 0002). A lactic acid bacteria culture is added, and the product is "used as compound yogurt food [sic]". After fermentation, as disclosed for example at 12 hours (par. 0006), "just before solidifying, it [is] moved to the refrigerator, and fermentation was stopped." As this is to be a yogurt-type food, letting the fermented culture settle in the refrigerator would constitute the "aging" of the mixture. Note that the resultant product would inherently possess the "effective ingredients" of instant claims 14-15 and 17, absent any clear and convincing evidence and/or arguments to the contrary.

Claims 1-2, 6-7, 9-11, 13, 14-15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Naruse et al. (US PAT 4,110,477).

Naruse et al. discloses a method for producing natto, containing lactic acid bacteria. *Bacillus* and lactic acid bacteria strains are incubated on a culture medium of water, sugar, skimmed milk powder (see claim 6 of the reference), and a homogenized suspension of mushroom (*Lentinus edodes*; col. 1, ln. 39-44). See also col. 2-3, top col. 4. The cultured bacterial medium is subsequently added to steamed soybeans. At column 2, lines 19-21, it is stated that the bacterial cultures are available in the form of a

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suspension or a powder, and at column 4 it is stated that the thermostable species of lactic acid bacteria were "heat-shock treated". The mushroom medium suspension is made by grinding in a homogenizer, sterilized at 75-80°C for 30 minutes, and cooled to 40-45°C. The culture is added to the soybeans, and incubated at 40-42°C for 18-20 hours (col. 3, ln. 12-16). After fermentation, the product is refrigerated and stored at 5-10°C. Note that the resultant product would inherently possess the "effective ingredients" of instant claims 14-15 and 17, absent any clear and convincing evidence and/or arguments to the contrary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakada, taken as cited above, in view of Tamime et al. (Yoghurt Science & Technology).

Tamime et al. disclose standard procedures and knowledge in the art regarding culturing lactic acid bacteria for fermentation of milk into yogurt products. The two primary "yogurt bacteria" utilized in the industry are *S. thermophilus* and *Lactobacillus bulgaricus*. Figure 6.1 demonstrates the growth of *L. bulgaricus* "at 40°C in autoclaved skim milk" at a 2% inoculation rate.

As taught by Nakada above, a ground mushroom extract was produced and added to milk, or skim milk powder, and a sugar. Subsequently a lactic acid bacteria culture is added, and the product is "used as compound yogurt food [sic]". As the specifics of which bacteria to utilize were not provided by Nakada, one skilled in the art would be motivated to turn to a general text regarding the culturing of yogurt-producing lactic acid bacteria, for example, the teachings of Tamime et al. Several forms of commercial food-grade lactic acid bacteria were available in the art, both suspended in culture and in freeze-dried form. Thus, as the instantly-claimed bacterial strains, as well as the parameters of time and temperature, were commonly practiced in the art, it would have been obvious for one of ordinary skill to have utilized the teachings of Tamime et al. for the incubation and culturing of *Lactobacillus bulgaricus* within the ground mushroom-containing fermentation mixture of Nakada. This would not have involved an inventive step, as these parameters were well documented in the art.

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Conclusion

Claims 4-5, 16 and 18 are free of the prior art of record. While *Ganderma* mushroom has been known and used in various food preparations in the art, there is no teaching or suggestion to utilize this mushroom, or the others recited in combination as claimed, within the instantly-claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (571) 272-1401. The examiner can normally be reached on M-F (8:30am-6pm); First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


KEITH HENDRICKS
PRIMARY EXAMINER